

### REMARKS

Independent Claims 1 and 13 have been amended to advance prosecution by more specifically claiming the invention. In particular, Claims 1 and 13 have been amended to expressly recite that the microneedles have at least one sharp edge that enhances penetration of said microneedles through the stratum corneum layer of skin.

Claims 8-12 and 20-24 have been withdrawn as a result of an earlier restriction requirement.

Upon entry of these amendments, Claims 1-7 and 13-19 are pending in the present application. No additional claims fee is believed to be due.

### ART REJECTIONS

In the Office Action dated May 9, 2003, the Examiner rejected Claims 1-4, 6, and 13-18 under 35 USC §102(e) as being anticipated by Allen et al. (USPN 6,334,856). Applicants respectfully submit that in light of the above amendments and the following arguments, the above identified reference would not anticipate and/or lead one skilled in the art to the invention as set forth in the claims.

Allen et al. discloses a microneedle device for transporting therapeutic and biological molecules across tissue barriers. The Examiner states that Allen et al. discloses a microneedle array comprising a plurality of microneedles with a plurality of projections which are spaced by a range of 50-1000 microns and wherein the length of the projections is from 50-3000 microns. However, nowhere does Allen et al. address spacing of the microneedles other than what is shown in the figures. Importantly, Fig. 1B of Allen et al. shows that the length of the microneedles is less than 100 um with a separation of no more than 30 um. Whereas, independent Claims 1 and 13 of Applicants' invention specify that the separation distance between the microneedles is from 50-1000 um.

Furthermore, the microneedles disclosed in Allen et al. have smooth sides, see e.g., Fig. 1B. In contrast, independent Claims 1 and 13, as amended herein, specify that Applicants' microneedle structures have at least one sharp edge that enhances penetration of the microneedles through the stratum corneum layer of skin. Clearly the smooth sided, more narrowly spaced microneedle devices disclosed in Allen et al. can't anticipate the sharp edged, wider spaced microneedle structures recited in amended Claims 1 and 13.

Based on the foregoing, Applicants respectfully submit that Claims 1-4, 6, and 13-18 are not anticipated and/or obvious over Allen et al. and respectfully request that the Examiner's rejection under 35 USC §102(e) be withdrawn.

Next, the Examiner rejected Claims 1 and 13 under 35 USC §102(b) as being anticipated by Gerstel et al. (USPN 3,964,482). Applicants respectfully submit that in light of the above amendments and the following arguments, the above identified reference would not anticipate and/or lead one skilled in the art to the invention as set forth in the claims.

Gerstel relates to a drug delivery device for percutaneously administering a drug comprising a plurality of projections and a drug reservoir containing a drug. The Examiner states that Gerstel et al. discloses a microneedle array comprising a plurality of microneedles with a plurality of projections which are spaced by a range of 50-1000 microns and wherein the length of the projections is from 50-3000 microns. However, col. 7, lines 64-68 of Gerstel et al. states that the projection lengths are from 5um to 100 um and generally falling within the 20 um length. Figures 1, 2, and 6 of Gerstel et al. all show that for a given length of microneedles, the spacing is ~20% of that length. This would make the spacing of Gerstel's microneedles generally at 4 um apart from each other. Whereas, independent Claims 1 and 13 of Applicants' invention specify that the separation distance between the microneedles is from 50-1000 um.

Furthermore, like Allen et al., Gerstel et al., does not disclose sharp edged microneedles. In contrast, independent Claims 1 and 13, as amended herein, specify that Applicants' microneedle structures have at least one sharp edge that enhances penetration of the microneedles through the stratum corneum layer of skin. Clearly the smooth sided,

more narrowly spaced microneedle devices disclosed in Gerstel et al. can't anticipate the sharp edged, wider spaced microneedle structures recited in amended Claims 1 and 13.

Based on the foregoing, Applicants respectfully submit that Claims 1 and 13 are not anticipated and/or obvious over Gerstel et al. and respectfully request that the Examiner's rejection under 35 USC §102(b) be withdrawn.

Next, the Examiner rejected Claims 1-7 and 13-19 under 35 USC §103(a) as being unpatentable over Allen et al. as applied above, and further in view of Reed et al. (USPN 5,676,850). Applicants respectfully submit that in light of the above amendments and the following arguments, the above identified references would not have led one skilled in the art to the invention as set forth in the claims.

The Examiner states that Allen et al. discloses the claimed invention except for the hollow element having at least two sharp projections proximal to an end of the hollow element. Applicants respectfully submit that Allen et al. does not render obvious the claimed invention as amended herein, for all of the reasons set forth above.

The Reed et al. reference relates to a micromechanical barb designed for linking with an object. The Examiner states that Reed discloses hollow microelements each exhibiting an edged outer contour, said outer contour having at least 2 pointed shape projections that are used to more efficiently pierce and directly attach the needles to organs. However, Figs 7 and 13, and the text in Col 5, lines 5-33 all show and describe that that two pointed shape projections act as barbs and not as penetration enhancers. It is the single tip point of the barb that causes the penetration and not the side edges of the microneedles in the present invention. The functions of the side edges of the barbs in the Reed et al. reference are described in Col 1, lines 41-50, where it states that the barbs are shaped such that a locking connection is formed between a first member and second member.

Whereas, in Applicants' claimed invention, the microneedle structures have at least one sharp edge that enhances penetration of the microneedles through the stratum corneum layer of skin; not to lock the microneedles to organs as in Reed et al. Thus, even if one were to combine the microneedle devices of Allen et al. with the teachings of Reed et al. as the Examiner suggests, the combination would fall short of Applicants' claimed

invention. The result would be a narrowly spaced microneedles array having barbs at the end of the needles for locking the microneedles to organs and the like. In contrast, the more widely spaced microneedle structures claimed herein have sharp edges that enhance penetration of the microneedles into the skin, -- not serve as a locking connection as in Reed et al. Importantly, the sharp edged microneedles structures of the present invention also facilitate painless removal of the microneedles after the drug delivery is complete.

In short, it is respectfully submitted that a full consideration of the Allen et al. reference in combination with the Reed et al. reference would not lead the skilled artisan to Applicants' claimed invention.

#### CONCLUSION

In light of the above amendments and foregoing remarks, Applicants believe that all claims remaining in the present application -- namely, Claims 1-7 and 13-19 -- are now in form for allowance. Accordingly, it is respectfully requested that the claims be reconsidered, the rejections under 35 U.S.C. §102 and §103 be withdrawn, and the claims as amended be allowed. Should the Examiner have any questions or wish to further discuss this matter, it is requested that the undersigned attorney be contacted at (513) 634-9135.

Respectfully submitted,

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